

K010642

MAR 20 2001

510(k) Summary

Sponsor Information

Denver Biomedical, Inc.
14998 W. 6th Ave., Bldg. E700
Golden, CO 80401
303-279-7500

Contact Person: Jeff Hill, RA/QA Coordinator

This 510(k) summary was prepared on February 26, 2001.

Device Identification

The subject device is the Denver Pleurx Pleural Catheter.

Intended Use

The Pleurx Pleural Catheter is intended for long-term, intermittent drainage of symptomatic, recurrent, pleural effusions, including malignant pleural effusions and other pleural effusions that do not respond to treatment of the underlying disease.

Device Description

The Pleurx Pleural Catheter is a silicone tube that is partially implanted in the chest cavity. The external portion of the catheter includes a valve that remains closed until it is opened with a specific drainage line. When the drainage line is in place, a vacuum source can be used to drain fluid that builds up in the chest cavity.

Summary of the change

The Pleurx Pleural Catheter was originally labeled specifically for use in treating symptomatic, recurrent malignant pleural effusions.

Physicians began using the product for treating symptomatic, recurrent pleural effusions caused by non-malignant diseases. Analysis showed that the indications for use could be broadened to cover non-malignant pleural effusions without creating any new safety risks, provided that chylous pleural effusions continued to be contraindicated.

Because the device acts by physically removing an abnormal fluid accumulation, the nature of the underlying disease is not important for determining whether the Pleurx catheter will be effective.

Because the change in the indications statement does not raise new kinds of safety or effectiveness questions, it was determined that the labeling change did not change the intended use of the device. Therefore, the re-labeled Pleurx Pleural Catheter is substantially equivalent to the original Pleurx Pleural Catheter.



MAR 20 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Bonnie Vivian
Denver Biomedical, Inc.
14998 W. 6th Avenue, Building E-700
Golden, CO 80401

Re: K010642
Pleurx Pleural Catheter and Drainage Kits
Regulatory Class: II (two)
Product Code: 74 DWM
Dated: February 28, 2001
Received: March 5, 2001

Dear Ms. Vivian:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

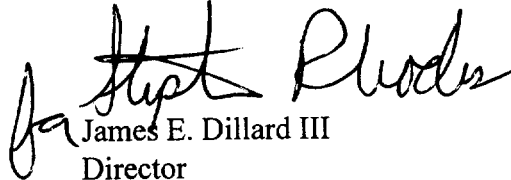
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for

Page 2 - Ms. Bonnie Vivian

Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Ja. Dillard", is written over the typed name "James E. Dillard III".

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010642


Device Name: Pleurx Pleural Catheter

Indications For Use:

The Denver® Pleurx® Pleural Catheter Kit and the Denver® Pleurx® Drainage Kit are indicated for intermittent, long-term drainage of symptomatic, recurrent pleural effusion, including malignant pleural effusion and other recurrent effusions that do not respond to medical management of the underlying disease. The devices are indicated for 1) the palliation of dyspnea due to pleural effusion and 2) providing pleurodesis (resolution of the pleural effusion).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K010642

(Optional Format 3-10-98)

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